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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,255	05/23/2005	Jean Fioramonti	045636-5081	1258

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER

TONGUE, LAKIA J

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/509,255

Applicant(s)

FIORAMONTI ET AL.

Examiner

Lakia J. Tongue

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 6-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 6-18 are pending and under examination. Claims 1-5 have been canceled.

Priority

1. Receipt is acknowledged of a certified copy of the France 02/03891 application referred to in the oath and declaration. Applicants are reminded that in order to obtain priority under 35 U.S.C. 119 (a)-(d) Applicants must submit an amendment to correct the first line of the specification. Applicants should include in the amendment of the instant specification the following: This application is a 371 of PCT/FR03/00903 filed 3/21/03, which claims foreign priority to France 02/03891 filed on 03/28/02.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims ~~6~~-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating colonic inflammation comprising administering an effective amount of a composition comprising lactic acid bacterium of the species *Lactobacillus farciminis*, does not reasonably provide enablement for a method of preventing pathologies of the digestive tube comprising administering an effective amount of a composition comprising lactic acid bacterium of the species *Lactobacillus farciminis*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several options to treating inflammatory diseases like irritable bowel syndrome (IBS), colonic inflammation and ulcerative colitis. However, there are no known preventive measures to be taken against disease such as those listed above. WebMDHealth (http://mywebmd.com/hw/inflammatory_bowel/uf6012.asp) discloses that Crohn's Disease cannot be prevented because the cause of the disease is unknown. In addition WebMD disclose that you cannot prevent ulcerative colitis because the cause of the disease is unknown. Moreover, HealingWithNutrition.com (<http://www.HealingWithNutrition.com/idisease/inflambowel/chrohns.html>) disclose that treatment for Crohn's disease depends on the location and severity of the disease,

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complications and response to previous treatments. The goals of treatment are to control inflammation, correct nutritional deficiencies and relieve symptoms like abdominal pain, diarrhea and rectal bleeding. At this time treatment can help the disease, but there is no cure (page 4).

InteliHealth (<http://www.intelihealth.com>) discloses that there is no single test to offer a definite diagnosis of IBS. Additionally it is stated that a person may be able to reduce the frequency and severity of symptoms by reducing stress or changing the diet, but because no one knows what causes IBS, it is impossible to prevent IBS (page 2).

The Wands factors have been considered in the establishment of this scope of enablement rejection:

- a. the quantity of experimentation necessary would be undue for the prevention of inflammatory digestive diseases;
- b. the amount of direction or guidance has not been presented;
- c. the presence or absence of working examples displaying the protection/prevention of colonic inflammation or any other inflammatory digestive disease has not been provided;
- d. the nature of the invention is one that without specific guidance would be problematic;
- e. the state of the prior art is one which states there is no proven/known prevention for inflammatory digestive disorders ;
- f. the relative skill of those in the art: high;

g. the predictability or unpredictability of the art: unpredictable as the causative agent for the diseases are unknown; and

h. breadth of the claims: broad.

In view of all of the above, in view of the lack of predictability in the art, it is determined that it would require undue experimentation to make and use the claimed invention commensurate in scope with the claims. Thus, the instantly claimed invention is enabled only for a scope of what is now claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 15-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Ubbink et al (U.S. 2005/0153018 A1).

Claims 15-18 are drawn to a composition for the treatment of pathologies of the digestive tube comprising lactic acid bacteria of the species *Lactobacillus farciminis*.

Ubbink et al discloses a probiotic delivery system. Ubbink et al disclose that suitable probiotics for use in the composition include but are not limited to yeast such as

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Saccharomyces and bacteria such as the genera Bifidobacterium, Streptococcus, Lactococcus and Lactobacillus. Moreover, Ubbink et al disclose that *Lactobacillus farciminis* is a probiotic strain that may be selected (0057). Ubbink et al disclose that the present invention provides a particulate food, food additive, supplement or pharmaceutical product (0021). Lastly, Ubbink et al disclose that foodstuffs such as fermented milk products that contain probiotics are commercially available (0004). Claim limitations such as “for the treatment of pathologies of the digestive tube” are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 458.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Roussel et al (WO 98/27991, not translated) has been cited throughout the instant specification and appears to have some commonality with the claimed invention.

Farmer (U.S. 2005/0232909 A1) discloses the use of lactobacillus to treat digestive disorders.

Venturi et al (Impact on the composition of faecal flora by a new probiotic preparation: preliminary data on maintenance treatment of patients with ulcerative colitis, Aliment Pharmacol Ther, 1999; 13: 1103-1108).

Nobaek et al (Alteration of intestinal microflora is associated with reduction in abdominal bloating and pain in patients with irritable bowel syndrome, The American Journal of Gastroenterology, 2000; 95(5): 1231-1238).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600